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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/781,579 01/09/97 GARDINER

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EXAMINER

QM12/0810

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ART UNIT

PAPER NUMBER

3731

DATE MAILED:

08/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/781,579

Applicant(s)
Gardiner et al.

Examiner
Tina Pham

Group Art Unit
3731



☒ Responsive to communication(s) filed on May 18, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-16, 18, 19, 21-23, 26-31, 36, 43-49, and 67-76 is/are pending in the application.

Of the above, claim(s) 68, 71, 73, and 76 is/are withdrawn from consideration.

☒ Claim(s) 19 and 21-23 is/are allowed.

☒ Claim(s) 1-8, 10-15, 18, 26-31, 36, 43-45, 47-49, 67, 69, 70, 72, 74, and 75 is/are rejected.

☒ Claim(s) 9, 16, and 46 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

Tina Pham
Tina Pham
Examiner
Art Unit 3731

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

This application contains claims 68, 71, 73, 76 are drawn to an invention non-elected with traverse in Paper No. 11 . A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 74 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "a surgical fastener made by skewering tissue" is vague and indefinite. It is unclear whether the applicant is claiming a method of making the fastener or the fastener itself.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Green et al. in Patent 5,658,312.

Note figures 1-3, a surgical fastener comprises a base (110) having at least one substantially planar surface, a flange (121) is bendably joined to a first edge of the base, a pin (121) is bendably joined to the base at a second edge of said base opposing the first edge, a needle (124) is removably joined to the pin (121), said base (110) is configured to be releasably engaged with an associated instrument.

Claims 29-31, 36, 69-70, 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Bregen in Patent 5,304,204.

Note figures 9-10, a staple comprising of a base (102) having a substantially planar surface; a flange (108) having a substantially planar surface attached to a first edge of said base, said flange is capable of moving; a pin (the other 108) is attached to a second edge of the base,

said pin adapted to releasably joined with a needle (110); said pin is capable of moving; a needle (110).

The functional language in claim 29 drawn to intended use, "adapted to releasably joined with a needle" cannot serve to distinguish over the prior art which includes all of the structural elements called for in the claims and can thus inherently perform in the same manner as the claim invention.

Regarding claim 31, element (102) is considered as a first section, element (108) is considered as a second section, the other element (108) with sharp portion (110) is considered as a single needle.

Claims 26-28, 67, 74-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrows et al. in Patent 4,719,917.

Note figure 3, a surgical fastener comprises a first member (4) with at least a portion adapted to pass through tissues, first member (4) includes a piercing end; a second member (8); a third member (6); said second and third members capable of moving from a first orientation, where portions of said members are spaced apart sufficient to receive tissue as shown in figure 2, to a second orientation where said members lie in contact with the tissue.

Claims 5-8, 10, 12-15, 43-45, 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by McGarry et al. in Patent 5,366,479.

Note all figures, an instrument for applying a surgical staple comprises of: an elongated shaft (14) having a distal end portion; a staple holder (16) at the distal end portion, a staple forming member (104) at the distal end portion (col. 19, lines 41-53); a handle having a control for actuating the staple forming member; said staple holder (16) can articulate and the handle has a control for actuating an articulating mechanism.

With respect to claim 5, the staple and the needle are set forth in the functional language, not as a definite part of the invention. The functional language drawn to intended use, "adapted to engage a staple and a needle . . . the base opposing said first edge" cannot serve to distinguish over the prior art which includes all of the structural elements called for in the claims and can thus inherently perform in the same manner as the claim invention.

Similarly, with respect to claim 12, the recitation "for holding a staple . . . a graft to an artery" is a functional statement. Therefore, it is given minimal patentable weight.

McGarry also discloses a method comprises the steps of: providing an instrument as described above; providing a staple holder (16) with at least one staple (see figure 28) comprises a base (110c), a flange (110BR), a pin (110BL), a needle (110L); incising a patient's tissue to create at least one opening; inserting the distal end of the instrument through the opening, so that the distal end is disposed in the patient, passing the needle (110L) through a portion of one tissue; actuating the staple forming member.

With regard to claim 43, member (110c) is the first section, member (110R) is the second section, member (110L) is the needle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

Claims 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGarry et al. in Patent 5,366,479.

McGarry discloses the invention as described above. However, McGarry does not disclose the claimed dimensions. It would have been an obvious matter of design choice to design the device to have the claimed dimensions, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

The question under section 103 is whether the subject matter as a whole would have been obvious, not whether the differences would have been obvious. In re McLaughlin, 170 USPQ 209 (CCPA 971); and In re Etter, 225 USPQ 1 (Fed. Cir. 1985).

Change in dimension, degree, size, ect. without special functional significance are not patentable. Research Corp. v. Nasco Industries, Inc., 501 F2d 358; 182 USPQ 449 (CA 7), cert. denied 184 USPQ 193; USLW 3359 (1974), In re Rose, 105 USPQ 137, and In re Aller et al., 105 USPQ 233.

Response to Arguments

Applicant's arguments filed May 18, 1999 have been fully considered but they are not persuasive.

In response to the applicant's arguments with respect to the Election/Restriction issue, the examiner agrees that all the pending claims, accept claims 68, 71, 73, 76, are generic.

Applicant's arguments with respect to claims 1-4, 29-31, 36 have been considered but are moot in view of the new ground(s) of rejection.

Regarding claims 26-28, the applicant argues that Barrow does not disclose a first member passing through tissue. Note figures 2-3, member (4) is considered as a first member, and it does indeed pass through tissues as shown.

Regarding claim 5, in response to applicant's argument that the "adapted for engage a staple and a needle" language distinguishes it from the reference , a recitation of the intended use

of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). As of now, the staple the needle are not positively recited in claim 5.

Regarding claim 12, the recitation "staple holder means at the distal end portion for holding" is given patentable weight. However, the claim is rejected by the McGary reference since it discloses a holder means (16) performing the function of holding. The recitation "a staple and a needle . . . an artery" is given minimal patentable weight since it is not recited positively in the claim.

Regarding claim 43, the McGary reference does disclose every features as claimed.

Regarding claims 11, and 18, a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). A change in the size of the shaft to facilitates endoscopic surgery is definitely not new in the art.

Change in dimension, degree, size, ect. without special functional significance are not patentable. *Research Corp. v. Nasco Industries, Inc.*, 501 F2d 358; 182 USPQ 449 (CA 7), cert. denied 184 USPQ 193; USLW 3359 (1974), *In re Rose*, 105 USPQ 137, and *In re Aller et al.*, 105 USPQ 233.

Allowable Subject Matter

Claims 9, 16, 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 19, 21-23 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications should be directed to Tina D. Pham at telephone number (703) 308-0824. The examiner can normally be reached Monday through Friday from 7:30 AM to 4:00 PM.

If an inordinate number of attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Michael Buiz can be reached at (703) 308-0871. The fax number for the Art Unit is (703) 308-0758.

Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist at (703) 308-0858.

Tina T. D. Pham

TP

August 01, 1999

OK
CLARENCE K. DAWSON
PRIMARY EXAMINER